K111142

Echometrix, LLC
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Madison, WI 53719 USA

SEP 21 2012

510K SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- Identification of Submitter

Echometrix, LLC
437 S. Yellowstone Drive, Suite 210
Madison, WI 53719
Contact: Larry A. Kroger, Ph.D., Regulatory Consultant
Ph. 262-549-6646
Revised July 12, 2012

- Identification of the Product

Proprietary name: EchoSoft™
Classification name: Picture archiving and communication system
Product Code: LLZ

- Marketed Devices

EchoSoft™ is a new software package which utilizes an acousto-elastography technique with diagnostic ultrasound images to analyze the mechanical properties of tendon and tendon-like tissues. It performs functions similar to software currently available on the following marketed diagnostic ultrasound devices:

- Philips iU22 Diagnostic Ultrasound System intended for diagnostic ultrasound imaging in B-mode (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging, Harmonics (Tissue and Contrast) and Elastography modes, PMN# K093563, classification number and name 21 CFR 892.1550 Ultrasonic pulsed doppler imaging system, product code IYN.
- Toshiba SSA-790A Aplio XG v4.0R001 Diagnostic Ultrasound System intended for diagnostic imaging in B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Dynamic Flow, 3D Imaging, and indicated for determining the relative elasticity of a lesion, PMN# K092179, classification number and name 21 CFR 892.1550 Ultrasonic pulsed doppler imaging system, product code IYN.
- Hitachi Hi VISION Preirus Diagnostic Ultrasound System intended for diagnostic imaging in B mode, M mode, PW mode (Pulsed

- Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real Time Tissue Elastography, and Real Time Virtual Sonography, PMN# K093466, classification number and name 21 CFR 892.1560 Ultrasonic pulsed echo imaging system, product code IYO.

° Device Description

The Echometrix, LLC software, EchoSoft, is an image processing algorithm that, when used with diagnostic ultrasound images, provides qualitative information about the mechanical characteristics of the deforming material by tracking motion, deformation, and ultrasonic echo magnitude change within a given region. This technology can be used by a physician to gather information about the mechanical and functional properties of soft tissues which, in conjunction with standard medical data, can be used to assist in clinical diagnosis.

° Intended Uses

EchoSoft™ is a software calculation package that is used with diagnostic ultrasound images to provide mechanical information about tendon and tendon-like tissues (such as ligaments) that may be used by a physician, along with other medical data, to assist in clinical diagnosis of various types of physical conditions or injuries.

° Comparison with Predicate

EchoSoft™ is a software calculation package that will be marketed as stand-alone software. Ultrasound images are accessed and incorporated into the analysis package via standard communication protocols such as DICOM. For the predicate devices similar software capabilities are incorporated into the system and are marketed as part of a total diagnostic ultrasound system.

° Summary of Studies

The EchoSoft™ software was evaluated with multiple studies to verify the ability of the algorithm to distinguish between materials with different mechanical properties. The studies consisted of laboratory measurements on phantoms containing materials with varying elastic properties to verify performance parameters such as resolution, sensitivity and precision. Several studies were conducted on bovine tendons to demonstrate performance on tissue samples with known defects. Sample clinical images were also provided to demonstrate performance of the software on tendons with previously diagnosed injuries. Some of the studies were conducted on ultrasound systems from different

manufacturers to verify reproducibility of the results. The ultrasound systems used in the studies were produced by GE (model Logiqe), Siemens (model S2000), and Terason (model t3000).

° Conclusions

It is the opinion of Echometrix that EchoSoft™ software is substantially equivalent to the elastography options available for the predicate devices. EchoSoft™ does not include any new indications for use with regards to evaluating the mechanical properties of tendon and tendon-like tissues, nor does use of this software result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2012

Echometrix, LLC
% Mr. Larry A. Kroger
Regulatory Consultant
2210 Woodhill Way
WAUKESHA WI 53189

Re: K111142
Trade/Device Name: EchoSoft™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 30, 2012
Received: July 31, 2012

Dear Mr. Kroger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111142

Device Name: EchoSoft™

Indications For Use: EchoSoft™ is a software calculation package that is used with diagnostic ultrasound images to provide mechanical information about tendon and tendon-like tissues of interest that may be used by a physician, along with other medical data, to assist in clinical diagnosis. The software is intended to be used by trained professionals only.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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